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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,125	06/28/2007	Stephen Lye	MTS6USA	1349

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EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,125	LYE ET AL.	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07-14-2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-18,20-26,39-44,46 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *14-18, 20-26,39-44, 46, and 53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is 371 filing of PCT/CA05/00042, filed 01/14/2005, which claims benefit to US Provisional Application 60/536,598 filed 01/15/2004.

The amendment filed 04/21/2006 has been received and entered. Claims 1-22 have been canceled. Claims 23-46 have been entered.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 14, in part, 15, 16 and 26, drawn to **a method** for preventing or treating a condition mediated by a steroid receptor in a subject comprising administering **a PSF Polynucleotide** or an agonist or antagonist thereof.

II. Claims 14, in part, 15, 16, and 26, drawn to **a method** for preventing or treating a condition mediated by a steroid receptor in a subject comprising administering **a PSF Polypeptide** and/or PSF complexes of a PSF polypeptide and a steroid receptor or an agonist or antagonist thereof.

III. Claims 17, in part, 18 and 21-25 drawn to a **method** for identifying a substance that modulates a steroid receptor comprising assaying for a substance that **inhibits a PSF Polynucleotide.**

IV. Claims 17, in part, 18 and 21-25 drawn to a **method** for identifying a substance that modulates a steroid receptor comprising assaying for a substance that **stimulates a PSF Polynucleotide.**

V. Claims 17, in part, 18 and 21-25 drawn to a **method** for identifying a substance that modulates a steroid receptor comprising assaying for a substance that **inhibits a PSF Polypeptide** or PSF complexes of a PSF polypeptide and a steroid receptor

VI. Claims 17, in part, 18 and 21-25 drawn to a **method** for identifying a substance that modulates a steroid receptor comprising assaying for a substance that **stimulates a PSF Polypeptide** or PSF complexes of a PSF polypeptide and a steroid receptor

VII. Claims 20, drawn to **a method** of conducting a drug discovery business comprising: (a) providing a method for identifying a substance; (b) conducting therapeutic profiling of substances for efficacy and toxicity in animals; and (c) formulating a pharmaceutical preparation including one or more substances having an acceptable therapeutic profile.

VIII. Claims 39-43, in part, drawn to **a method** for identifying pre-term labor or the onset of labor in a subject comprising **detecting a PSF Polynucleotide** in a sample from the subject.

IX. Claims 39-43, in part, drawn to **a method** for identifying pre-term labor or the onset of labor in a subject comprising **detecting a PSF polypeptide, and/or PSF Complex** in a sample from the subject.

X. Claims 44 and 46 in part, drawn to **pharmaceutical composition** comprising an effective amount of a PSF Polypeptide, PSF Complex, and/or PSF Polynucleotide, or an agonist or antagonist thereof.

XI. Claim 53 drawn to **a kit.**

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons:

37 CFR 1.475 (c) states:

"If an application contains to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present"

37 CFR 1.475 (d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c)".

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical reasons: the technical feature linking Groups I-XI appears to be that they all relate to methods, compositions, and uses for modulating a steroid receptor or process mediated by a steroid receptor in a cell by administering a polypyridimine tract binding protein-associated splicing factor (PSF) polypeptide, a polynucleotide encoding the polypeptide and/or an isolated complex of a PSF polypeptide and a steroid receptor. . However, prior art has taught that PSF is a novel corepressor that mediates its effect through Sin3A and the DNA binding domain of nuclear hormone receptors (Mathur et al., MOL CELL BIOL. 2001, Vol. 21, No. 7, pages 2298-2311, of record). Therefore, the technical feature linking the invention of groups I-XI does not

constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over prior art for the reasons set forth above.

The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions of Groups I-XI are drawn to materially different and distinct inventive concepts, having different chemical structures, physical properties and biological functions. For example, inventions of Groups I, III, IV and VIII are drawn to methods of administering a PSF polynucleotide, assaying for substances that inhibit a PSF polynucleotide, assaying for substances that activate a PSF polynucleotide and detecting a PSF polynucleotide in a sample, respectively, that are structurally and functionally different from inventions of Groups II, V, VI and IX drawn to methods of administering a PSF polypeptide and/or PSF polypeptide complex , assaying for substances that inhibit a PSF polypeptide and/or PSF polypeptide complex, assaying for substances that activate a PSF polypeptide and/or PSF polypeptide complex and detecting a polypeptide and/or PSF polypeptide complex, respectively, as the result of being methods comprising either polynucleotides or polypeptides which require separate searches; they are not obvious variants and deemed patentably distinct for the following reasons: polynucleotides, which are composed of purine and pyrimidine units and polypeptides/proteins, which are composed of amino acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Moreover, because of the degeneracy of the genetic code, different

nucleotide sequences can encode the same polypeptide sequence. Hence, the information provided by a polynucleotide in the method of Groups I, III, IV and VIII can be used to make a materially different polypeptide than that in the method of Groups II, V, VI and IX. Moreover, inventions of **Group X** drawn to a **pharmaceutical composition** include unique technical features that are not shared by the inventions of Groups XI drawn to **a kit** or the invention of **Group VII** drawn to a **method** of conducting a drug discovery business comprising, for example, conducting therapeutic profiling of substances for efficacy and toxicity in animals, which active step is not disclosed as required by the inventions of Groups X or XI.

The claims in Groups I-XI are drawn to distinct products and methods that utilize distinct steps, requiring non-coextensive search and examination. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-XI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

In addition, **if either Group III or IV is elected**, a **further restriction** is required among proteins sequences of **SEQ ID NO: 1, 2, 3, 4, 5, 6, 10, 11, 12, 13, 14, 15 and 21** which are each distinct polypeptide sequences encoded by specific and unique polynucleotides. The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As the technical feature of a nucleotide sequence coding for a polypeptide, linking the members does not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the each nucleic acid does not overlap in scope with the others, are not

obvious variants, and have materially different functions, the requirement for unity of invention is not fulfilled. **Applicants must elect one specific polypeptide SEQ ID NO.**

MPEP 1893.03(d) states:

If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821

Species restriction

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

if either Group III or IV is elected, be elected, a species restriction is further required under 35 U.S.C. 121 and 372, wherein a species election(s) must correspond to an elected group as indicated above. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

1) a RRMII domain, a polypeptide consisting of amino acids 1-150, amino acids 290-370, amino acids 1-662 of SEQ ID NO. 1, as recited in claim 22.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species results in a unique compound

with unique chemical properties with unique uses and limitations that do not extend one to the other. The substitution of binding domain of the PSF polypeptide that interacts with a steroid receptor to another is not necessarily an obvious substitution that results in a method for identifying a substance that modulates of equivalent properties.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 14, 17 and 39 are generic.

2) a DBD domain or a AF3 domain, a polypeptide consisting of amino acids 1-164 of SEQ ID NO. 10, amino acids 456-650 of SEQ ID NO. 10, amino acids 567-587 of SEQ ID NO. 10, amino acids 556 to 933 of SEQ ID NO. 10, as recited in claim 25.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species results in a unique compound with unique chemical properties with unique uses and limitations that do not extend one to the other. The substitution of binding domain of the progesterone receptor that interacts with the PSF polypeptide to another is not necessarily an obvious substitution that results in a method for identifying a substance that modulates of equivalent properties.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 14, 17 and 39 are generic.

Applicant is required, in reply to this action, to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 1 and 13 are generic.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, Ph.D.
Examiner, Art Unit 1633